REMARKS/ARGUMENTS

A petition for a three month extension of time and authorization to charge the appropriate fee is submitted herewith.

The specification has been amended to correct a misreference to values in Tables 3, 5 and 7. The R^2 values were inadvertently referenced instead of the k values.

Examiner objected to Figures 3-5 because the y axis recites "ppm Ag in lns". Applicants submit herewith copies of Figures 3-5 as originally submitted, which clearly state "ppm Ag in lens". Applicants submit that the objection has been traversed.

Rejections under 35 U.S.C. 103

Examiner has rejected claims 1-4, 8-16, 19-23 and 25-30 as unpatentable over Shimai et al. (JP07-270726A), in view of Christ (US 5,843,186) and Dziabo et al. (US 5,340,583).

Shimai et al. discloses results from a method for injecting contact lenses with silver ions using an "ion injection apparatus". The results are reported in units of ions/cm^2, indicating that the ions are at the surface of the lens, and not within the lens bulk. Moreover, the description of the process provides no details which would enable one of skill in the art to vary the depth of the ions which are deposited on the lens. Shimai et al. fails to disclose the conditions used to test the lenses for antimicrobial activity, (including the composition of the incubation solution, lens preparation prior to incubation, the concentration or types of microbes in the incubation solution, the volume, temperature and time the samples were incubated, and what test was used to measure the number of colonies). There is no suggestion in Shimai et al. that antibacterial efficacy was measured at more than one time point.

Shimai et al. also fails to disclose how long antimicrobial efficacy lasts, discloses no release rates and contains no data from which release rates could be calculated. Thus Shimai et al. contains no teaching or suggestion on how to make an ophthalmic device which displays the controlled release rates (expressed via a rate constant k) as recited in the present invention.

Examiner has stated that "the ophthalmic devices of Shimai et al. containing silver encompasses the ophthalmic devices containing silver releasing compound of the instant claims and therefore it would be obvious to optimize the amount of injected silver ions to maximize antimicrobial efficacy". Page 20.

Applicants respectfully disagree. Increasing the amount of silver ions initially present does not by itself provide the release rate constant specified in the instant claims.

> "It has been found that the release of silver ions from an ophthalmic device may be modulated by controlling (a) the solubility of the silver releasing compound, the (b) electron density of the atom bound to the silver ion and (c) the initial concentration of the silver incorporated into the ophthalmic device." Page 5, lines 20-23, present specification.

This is clearly shown in the Examples of the present application. While there is some change in k value between Examples 1 through 4 (where Ag concentration was varied from 272 ppm to 1213), the k value far more significantly changed by changing the silver salt used (Examples 4-9, which use AgI). :

> "By comparing the k values of Example 11 (0.26), with those of Examples 1-4 (k values ranging from 0.05 to 0.13) it can be seen that the method of incorporation of the silver releasing compound influences the k value. This can also be seen by comparing the k values of Example 14 (2.0) with that of Examples 6-9 (0.12-0.20). ***In both instances compounding the silver releasing compound into the lens formulation provided lower k values***." (emphasis added). Page 24, lines 6-11.

The differences in k value can also be seen by comparing Examples 11-14. The rate constant for Examples 13 and 14 are much higher (2.1 and 2.0) than Example 12 (0.17), even though the initial amount of silver is the same (Example 13) or nearly double (Example 14). This clearly shows the substantial impact of factors other than concentration on rate constant.

Shimai et al. discloses no salts or ligands, and therefore provides no suggestion whatsoever as to how rate constants within the ranges recited in the present claims could be achieved.

Christ discloses intraocular lenses containing antimicrobial iontophoretic materials ("first and second metals that has a chemical half-cell potential difference". Column 5, line 66-column 6, line 1). Initial ionized silver concentrations and k values are not disclosed. Christ also provides no suggestion as to how desirable silver release rate constant could be achieved in an ophthalmic device.

Dziabo et al. discloses contact lenses including "substantially silver-free, substantially non-leachable antimicrobial component." Col. 4, lines 1-2.

"The presently useful antimicrobial components are preferably substantially non-leachable. Thus, the presently useful antimicrobial component preferably is such that it does not migrate, for example, from the lens of the lens case with which it is originally associated, into a liquid contacting the antimicrobial component under normal use conditions. Such substantially non-leachable antimicrobial components do not contaminated fluids in the eye or liquids used to care for contact lenses under normal use conditions. Antimicrobial components which release from the contact lens are neither disclosed nor suggested." Dziabo et al. col. 3, lines 9-18.

Dziabo et al. further discloses that the substantially non-leachable antimicrobial component is "preferably covalently bonded to the polymeric material included in the body of the contact lens". Col. 4, lines 37-40. Applicants have amended claim 1 to include the recitation of claim 2. Dziabo et al. clearly teaches that the antimicrobial component is "substantially non-leachable" which would have a release constant k below those currently claimed (and likely 0).

Examiner has stated that "it would have been obvious to one of ordinary skill in the art to utilize contact lenses of silicone-containing or PMMA polymeric material with a coating (Christ) and containing a silver binding ligand to control the release of the silver ions into solution and thus avoid any allergic reactions." Page 5, point 8, January 17, 2008 Office Action.

Applicants do not see how this would be obvious to one of skill in the art from the combined disclosures of Shimai et al., Christ and Dziabo et al. None of Shimai, et al., Christ or Dziabo et al. disclose (a) silver binding ligands, (b) the use of silver binding ligands to control silver ion release or the suggestion of avoidance of an allergic reaction. As noted above, not one of these references discloses k values, or includes information from which k values could be calculated. The references also completely fail to recognize how desirable k values could be achieved. Thus, the combination of Shimai et al., Christ and Dziabo et al. simply do not disclose or suggest the recited conditions of claim 1.

Claims 24, 8-9, 11-16, 19-23 and 25-30 depend from claim 1 and are patentable for the reasons discussed above.

With respect to claim 10, Shimai et al., Christ and Dziabo et al. are absolutely silent as to the potential risk of argyria, let alone the fact that there is an initial silver concentration which allows the extended efficacy, without causing argyria. Accordingly, claim 10 is patentable over the combination of Shimai et al., Christ and Dziabo et al.

Examiner has further rejected claims 1-4, 8-14, 16-23 and 25-30 as unpatentable in view of Shimai et al. and Christ in view of Tanaka et al.

Tanaka et al. discloses copolymers suitable for use as soft contact lenses. Abstract. Antimicrobial compounds of any kind, and desirable release rate constants are neither disclosed nor suggested.

As discussed above, Shimai et al. and Christ neither disclose nor suggest ophthalmic devices having the rate constants recited in the present application, nor give any suggestion on how they could be achieved. Tanaka et al. does not cure this deficiency.

Accordingly, Applicants respectfully submit the rejection based upon the combination of Shimai, et al, Christ and Tanaka has been traversed.

Examiner has further rejected claims 1-4, 8-14, 16 and 19-30 as unpatentable over Shimai et al., in view of Christ and Maiden et al. (US 6,367,929)

Shimai et al. and Christ have been discussed above, and do not disclose or suggest ophthalmic devices having the rate constants recited in the present application, nor give any suggestion on how they could be achieved.

Maiden et al. discloses silicone hydrogels made by including a high molecular weight hydrophilic polymer into the silicone hydrogel monomer mix". Abstract. Antimicrobial compounds are not disclosed or suggested. Even if one of skill in the art used the silicone hydrogels of Maiden et al. in the lenses of Shimai et al. or the IOLs of Christ, there is still no suggestion as to the silver release rate constant disclosed in the present claims or how it should be achieved.

Claim 24 depends indirectly from claim 1 and further recites that the contact lens comprises silicone hydrogel is selected from the group consisting of senofilcon A, galyfilcon A, lotrafilcon A and balafilcon A. There is nothing in Christ which suggests that the initial ionized silver concentration and release rates specified in claim 1 could provide ophthalmic devices with the extended silver release and antibacterial efficacy achieved by the present invention. As discussed above, neither Christ nor Shimai suggest the release rates currently claimed, nor how they could be achieved. Accordingly, Applicants respectfully submit claim 24 is patentable over the combination of Shimai, et al., Christ and Maiden et al.

Examiner has rejected claim 1-4, 8-14, 16, 19, 20-23 and 25-35 15 as unpatentable over Shimai et al., in view of Christ and Nissen et al.

Shimai et al. and Christ have been discussed above, and do not disclose or suggest ophthalmic devices having the rate constants recited in the present application, nor give any suggestion on how they could be achieved.

Nissen et al. does not disclose any information relating to the form of the silver on the lens, the concentration of silver on the lenses, the method by which the silver layer was applied or released from the lens. Without that information it is impossible to repeat Nissen et al. and calculate the release constant.

The present invention is concerned with

> "contact lenses that display extended release of silver ions. As used herein extended release means release of silver ions in an amount sufficient to inhibit microbial colonization over an extended period of time, such as two days, preferably seven days, more preferably 14 days and in some cases as many as or more than 30 days. Thus, the present invention allows for the manufacture of ophthalmic devices that provide resistance to microbial colonization over their entire wear schedule for the ophthalmic device." Page 3, lines 11-13.

There is absolutely no data in Nissen et al. which would suggest that the lenses disclosed therein would be antimicrobial for an extended period of time, and therefore have the release rate constants recited in the present claims. In fact, Nissen et al. does not disclose any efficacy data beyond 24 hours.

Thus, Nissen et al. contains no disclosure of rate constant as recited in the present invention, insufficient information to remake the lens to measure a rate constant, and no direction or suggestion as to how a desirable rate constant might be achieved.

Applicants respectfully submit that Examiner has not made a prima facie showing of obviousness based upon the combination of Shimai, et al., Christ and Nissen et al.

Claims 1-4, 8-14, 16-23 and 25-30 have been rejected as unpatenatable over Barry et al. in view of Tanaka, et al.

Barry et al. discloses antimicrobial ocular lenses containing metal ions retained on a ceramic carrier. Column 5, lines 35-38. The antimicrobial metal ion is disclosed to be present

"in a concentration from about 0.01 to 5 wt% of the zeolite" (col. 8, lines 35-36) and the zeolite is "present in an amount from about 0.1 to about 3% by weight of the polymeric material." Col. 8, lines 42-44. This gives an initial concentration of silver ions of 0.01 ppm to 25 ppm, below the range recited in the present claims. Barry et al. is absolutely silent as to how to get a lens having the k values recited in the present claims. With respect to Barry et al. Examiner has stated that "it is obvious to vary and /or optimize the amount of (compound) provided in the composition, according to the guidance provided by the (reference) to provide a composition having the desired properties". Page 21. Barry et al. does indeed provide guidance as to the initial silver concentration, 0.01 ppm to 25 ppm, which is below the range recited in the present claims. Barry et al. gives no guidance as to selecting compounds which would provide the desired rate constant. The only disclosure which gives guidance is the present application, at, for example page 5, lines 20-23:

> "It has been found that the release of silver ions from an ophthalmic device may be modulated by controlling (a) the solubility of the silver releasing compound, the (b) electron density of the atom bound to the silver ion and (c) the initial concentration of the silver incorporated into the ophthalmic device." Page 5, lines 20-23, present specification."

The examples also clearly show that the desired release rates are achieved only by combining suitable silver releasing compounds and the initial silver concentration. This result is simply not suggested by Barry et al.

Tanaka as discussed above, does not disclose or suggest any antimicrobial component, let alone those in the concentrations and having the rate constants recited in the present claims.

Examiner has further rejected claims 1-4, 8-14, 16 and 19-30 have been rejected as unpatentable over Barry et al. in view of Maiden, et al.

Barry et al. has been discussed above, and does not disclose or suggest the claimed ophthalmic devices.

Maiden et al. has been discussed above and does not disclose antimicrobial compounds, let alone those in the concentrations and having the rate constants recited in the present claims.

Even if one of skill in the art used the lens materials of Maiden et al. with the zeolites of Barry et al. they still would not have the initial concentrations recited in the present claims, nor would there be any suggestion as to how to achieve the recited rate constants.

Examiner has further rejected claims 1-4, 8-14, 16 and 19-35 have been rejected as unpatentable over Barry et al. in view of Nissen, et al.

Both Barry and Nissen et al. are discussed above. Neither reference discloses the initial silver concentration recited in the claims or discloses or suggests the recited rate constants or how they could be achieved.

Applicants respectfully submit that the foregoing amendments and arguments traversed the Examiner's rejections. None of the references taken alone or in combination provide the general conditions of the present claim (particularly the release rate constant) nor any suggestion whatsoever, as to how desirable rate constants could be achieved. Withdrawal of the rejections is requested.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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